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Applicant: Mark J. Jaroszeski et al.
Serial No. 09/939,518
Filing Date: 08/24/2001
Practitioner's Docket No.: 1372.34

Group Art: 1635
Examiner: Jon E. Angell

REMARKS

Applicant has carefully studied the nonfinal Examiner's Action mailed December 17, 2002, the Advisory Action mailed March 13, 2003 and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

Declaration Under 37 CFR 1.132

The Declaration filed under 37 CFR 1.132 stands deemed as insufficient. In view of the current amendments to the claims, the Declaration Under 37 CFR 1.132 is rendered moot and is therefore withdrawn.

Claim Rejections – 35 U.S.C. § 112

Applicant acknowledges the quotation of 35 U.S.C § 112.

Claims 2 and 12 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. More specifically, the phrase, "a duration of at least 100m seconds", constitutes new matter because there is now no upper limit to the duration of time for which the electric field can be applied. Therefore, the claims encompass applying an electric field for a duration of at least 100ms up to infinity. Reconsideration and withdrawal of this ground of rejection is requested for the reasons that follow.

Claims 1, 2, 11 and 12 have been rewritten to identify an upper limit for the application of the electric field. In view of the amended claims, applicant now believes that claims 1, 2, 11 and 12 are definite with regard to the written description. As such, applicant believes that the rejection of claims 1, 2, 11 and 12 have been overcome by amendment.

Claim Rejections – 35 U.S.C. § 102

Applicant acknowledges the quotation of 35 U.S.C. § 102.

Claims 1, 4-8, 10, 11, 14-18 and 20 stand rejected under 35 U.S.C. 102(a) as anticipated by Lucas et al. (DNA and Cell Biol. Vol. 20(3):183-8; March 2001). Applicant's arguments filed 10/9/02 traversed the Lucas reference as prior art under 37 CFR 1.132. However, it was noted by the Examiner that the declaration under 37 CFR 1.132 submitted in the previous Amendment was insufficient to overcome the rejection. The claims have been amended to include limitations not described by Lucas et al., and as such Applicant believes that claims 1, 4-8, 10, 11, 14-18, 20 and newly added claims 21-36, are not anticipated by Lucas and are in condition for allowance.

Claims 1, 4-5, 14, 16-18 and 20 stand rejected under 35 U.S.C. 102(a) as being anticipated by Heller et al. (DNA and Cell Biol. Vol. 20(1): 21-6; January 2001). Applicant's arguments filed 10/9/02 traversed the Heller reference as prior art under 37 CFR 1.132. However, it was noted by the Examiner that the declaration under 37 CFR 1.132 submitted in the previous Amendment was insufficient to overcome the rejection. The claims have been amended to included limitation not described by Heller et al., and as such Applicant believes that claims 1, 4-5, 14, 16-18, 20 and newly added claims 21-36 are not anticipated by Heller and are in condition for allowance.

Claims 1, 4-5 and 14-20 stand rejected under 35 U.S.C. 102(a) as anticipated by Betten et al. (Bioelectrochemistry Vol. 52:83-90; September 2000). Applicant herein traverses the rejection.

The Office contends that the claims of the present invention are drawn to a method/system of facilitating the delivery of a molecule into a target tissue comprising applying "a substantially continuous low-level electric field to the target tissue for a duration sufficient to facilitate entry of a desired molecule into the interior of the cell". It is noted by the Office that the claims do not set forth the parameters which define the "substantially continuous low-level electric field". Turning to the specification for guidance, the specification discloses, "the characteristics of the filed used to facilitate the entry of the molecules into the target cell include field strengths between 1mV/cm and 200V/cm, applied as pulses of substantially continuous energy. The duration of the pulse ranges from 0.1s to 20 minutes, with 100ms to 100s duration comprising a preferred range. As such, the defining parameters of a substantially continuous field as taught by the present invention are interpreted by the Office to be a field which would facilitate entry into a target cell when applied as any single pulse in the range of 1mV/cm and 200V/cm and for a duration of 0.1s to 20 minutes. Therefore, the Office contends that any electric pulse within these parameters would inherently have the same effect and result in the desired outcome.

The Office states that Bettan describes submitting each tumor to eight pulses of 20ms duration at a voltage-distance ratio ranging from 200 to 800V/cm, which is within the range defined by the specification of the present invention as able to facilitate porosity of a target cell and facilitate entry of a molecule into said cell. And as such, a single pulse of the method taught by Bettan would inherently result in entry of a molecule into the cell, regardless if multiple pulses were applied.

Applicant respectfully points out that pulse duration taught by Bettan, 20ms, does not fall within the range defined by the specification of the present invention, 100ms to 20 minutes. As such, the present invention is not anticipated by Bettan.

Claims 1, 4-6, 8-11, 14-16 and 18-20 stand rejected under 35 U.S.C. 102(b) as anticipated by Mir et al. (PNAS Vol. 96:4262-4267; April 1999). Applicant herein traverses the rejection.

The Office states that Mir teaches the application of an electric field at 100V/cm, but optimal at 200V/cm, for a duration of 20ms. The Office contends that the range taught by Mir is within the range define by the specification of the present invention as able to facilitate porosity of a target cell and facilitate entry of a molecule into said cell. Therefore, a single pulse of the method taught by Mir would inherently result in entry of a molecule into the cell, regardless if multiple pulses were applied.

Applicant respectfully points out that the pulse duration taught by Mir, 20ms, does not fall within the range defined by the specification of the present invention, 100ms to 20 minutes. As such, the present invention is not anticipated by Mir.

Claims 1-20 stand rejected under 35 U.S.C. 102(b) as anticipated by Hofmann et al. (U.S. Patent 6,055,453). Applicant herein traverses the rejection.

The Office states that the electric field strength taught by Hofman can be from 10V/cm to about 20kV/cm and the pulse duration can be about 10μs to about 100ms. The Office contends that the range taught by Hofman is within the range defined by the specification of the present invention as able to facilitate porosity of a target cell and facilitate entry of a molecule into said cell. Therefore, a single pulse of the method taught by Hofmann would inherently result in entry of a molecule into the cell, regardless if multiple pulses were applied.

Hofmann describes at col. 10, lines 3-56 the application of a low-level electric pulse of long duration. However, the descriptions of Hofmann all suggest the use of a series of pulses to facilitate the entry of the molecule into the cell. Hofmann does not describe or suggest the use of

a single low-level electric field that is applied for a duration of between 100ms and 20 minutes to effect the entry of a molecule into the cell. As such, independent claims 1 and 11 have been amended to further limit the claims to the application of a single pulse within a range of 100ms to 20 minutes. Claims 5, 7, 15 and 17 directed to the application of a plurality of pulses within this pulse duration range have been cancelled.

For the reasons cited above, Applicant believes that independent claims 1 and 11 are now in condition for allowance.

Claims 2, 4, 6, 8 and 10 are dependent upon claim 1 and are therefore allowable as a matter of law.

Claims 12, 14, 16, 18 and 20 are dependent upon claim 11 and are therefore allowable as a matter of law.

Claims 21-36 have been added. Claims 21-36 are drawn to a system and method for facilitating the delivery of a desired molecule into a target tissue whereby the application of the electric field is limited to a pulsed duration between 200ms and 20 minutes. The range described by Hofmann does not anticipate the claimed pulse duration recited in independent claims 21 and 29. As such, the newly added series of claims are in condition for allowance.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

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Very respectfully,

SMITH & HOPEN

By: Molly Sauter

Dated: June 13, 2003

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CERTIFICATE OF FACSIMILE TRANSMISSION
(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment D is being transmitted by facsimile to the United States Patent and Trademark Office, Technology Center 1600, Art Unit 1635, Attn: Jon E. Angell, (703) 872-9306 on June 13, 2003.

Dated: June 13, 2003

Deborah Preza